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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,936	12/21/2001	Roger Briesewitz	STAN066DIV	8489

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/07/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025 934

Applicant(s)

Brisowitz et al

Examiner

KCP

Group Art Unit

1657

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on 7/11/03

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 16-44 + 48-53 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 16-44 + 48-53 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

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The amendment of 7/11/03 amended claims 16, 20, 23, 29, 33, 35, 36 and 38, and added new claims 48-53.

Claims examined on the merits are 16-44 and 48-53 which are all claims in the application.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 16-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the drug moiety and presenter protein ligand of the bifunctional molecule being linked
10 together, does not reasonably provide enablement for a bifunctional molecule where the drug and ligand are not linked. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention
15 commensurate in scope with these claims.

The specification (page 3, lines 15-16) discloses linking the ligand to the drug, and there is no disclosure of the bifunctional molecule where the ligand and drug are not linked.

Claim Rejections - 35 USC § 112

20 Claims 16-44 and 48-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by not requiring the drug
25 moiety and presenter protein ligand of the bifunctional molecule to be linked together. If not linked together as disclosed in the

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specification, it is uncertain as to how the drug and ligand would exist together as a bifunctional molecule.

Requiring producing a "binary complex" in claim 1 and in other claims where a binary complex is required, it is unclear as to structure that is binary. In the claims the drug of the bifunctional molecule binds to a target and the ligand binds to presenter protein. This appears to involve three different components being bound together, i.e. the bifunctional molecule, drug target and presenter protein. How can three components bound together be a binary complex?

Furthermore, the claims are unclear as to the difference that occurs when a binary complex results such as in claims such as 1 and 35 as compared to producing a tripartite complex such as in claims 20 and 23. The claims drawn to producing the binary complex and claims drawn to producing the tripartite complex both involve the drug of the bifunctional molecule binding to a target and the ligand binding to a presenter protein. The same binding appears occur irrespective of whether a binary or tripartite complex is formed.

Claim 17 is unclear by not having clear antecedent basis for "said enhanced drug activity".

Claim 20 is unclear how it further limits claim 20 since claim 1 appears to require producing a complex containing the bifunctional molecule, present protein and target.

Claim 20 is further unclear by "tripartite complex is characterized by the presence of presenter protein target binding interactions" being uncertain as to meaning and scope. It is uncertain as to binding interactions that are within and outside the

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scope of this limitation. It appears that presenter protein target binding interactions inherently occur in the method of claim 1.

Claim 29 is unclear in lines 5 and 6 by not having clear antecedent basis for "the target" and "the target of said endogenous
5 presenter protein". Moreover, it appears the presenter protein is itself a target of ligand rather than the presenter protein having a target.

In claim 30, there is not clear antecedent basis for "said target protein".

10 The claims are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE
FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension
15 of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after
20 the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX
25 MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



David M. Naff
Primary Examiner
Art Unit 1651

DMN

15 10/6/03